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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/700,999

12/04/2000

Stephen M. Wiener

4239-56467

4557

36218

7590

06/29/2006

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,999

Applicant(s)

WIENER ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/20/2000</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III (claims 61-69) in the reply filed on 1/11/2006 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61, 63, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor (3,952,742). Taylor discloses an access device for targeted delivery of therapeutic or diagnostic agents, the device comprising an elongated cannula (12) having a wall, proximal and distal ends, and a lumen configured to contain a sharp-tipped trocar (14) for penetrating a wall (HW) of a desired body organ (heart) having a hollow space therein, first and second balloons (24,22) spaced axially along the cannula at positions such that, when the cannula is inserted through the wall of the organ and the balloons are inflated, the first balloon engages an inner face of the organ and the second balloon engages an outer face of the organ, holding the distal end of the cannula in position within the hollow space inside the organ and substantially sealing against leaks, further comprising inflation ports (30,32) positioned at or near the

proximal end of the cannula for inflating the first and second balloons, and wherein the cannula consists of bio-compatible material.

Claims 61, 63, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Landymore et al. (4,836,204). Landymore discloses an access device for targeted delivery of therapeutic or diagnostic agents, the device comprising an elongated cannula (12) having a wall, proximal and distal ends, and a lumen configured to contain a sharp-tipped trocar for penetrating a wall (S) of a desired body organ (heart) having a hollow space therein, first and second balloons (26,24) spaced axially along the cannula at positions such that, when the cannula is inserted through the wall of the organ and the balloons are inflated, the first balloon engages an inner face of the organ and the second balloon engages an outer face of the organ, holding the distal end of the cannula in position within the hollow space inside the organ and substantially sealing against leaks, further comprising inflation ports (not numbered) positioned at or near the proximal end of the cannula for inflating the first and second balloons, and wherein the cannula consists of bio-compatible material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 62 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (3,952,742) or Landymore et al. (4,836,204) in view of Parks et al. (5,250,040). Taylor and Landymore disclose most of the limitations as recited in claim 61, but fail to disclose a drainage line and inlet on the distal end of the cannula and an occluder comprising a cannula cap. Parks discloses a drainage line and inlet (36) on the distal end of the cannula, which allows drainage of a hollow body organ that is being penetrated. Parks also discloses a cap (40) to occlude the lumen of the cannula when not in use to reduce the risk of infection. Therefore, it would have been obvious to one

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of ordinary skill in the art at the time of the invention to modify the cannula of Taylor and Landymore with the modifications as disclosed by Parks to make an access device that could drain unwanted fluid from an organ and reduce the risk of internal infection.

Claims 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (3,952,742) or Landymore et al. (4,836,204) in view of Pierpont (5,484,412). Taylor and Landymore disclose most of the limitations as recited in claim 61, but fail to disclose an access device further comprising a flexible balloon catheter capable of being inserted through the cannula to occlude a duct communicating with the body organ. Pierpont discloses an access cannula with two balloons (36,38) and a flexible balloon catheter that is capable of occluding a duct that is distal to the end of the cannula. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the access devices of Taylor and Landymore with the modifications as disclosed by Pierpont to make an access device that could, during an operation, isolate an organ to reduce the risks of injury to the organ and surrounding tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

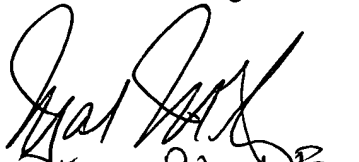
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Theodore J. Stigell


Primary Patent Examiner
Den 3763